UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Hon. Patti Saris
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories Inc., CIVIL ACTION NO. 06-11337-PBS	)	

UNITED STATES' RESPONSE TO ABBOTT LABORATORIES INC.'S REQUEST FOR CERTIFICATION OF INTERLOCUTORY APPEAL

PRELIMINARY STATEMENT

Abbott Laboratories Inc. (Abbott) has requested that this Court certify for interlocutory appeal (Request) two questions: (1) whether the United States be required to produce for *in camera* review over a thousand privileged documents unrelated to the specific Abbott drugs or allegations in this case and (2) whether, as a factual matter, the United States properly asserted the deliberative process privilege. The Request does not meet the standards for certification of the matter for interlocutory appeal.

The questions for which appeal is sought relate to an ancillary discovery dispute between Abbott and the United States.[1] Abbott seeks to go on a fishing expedition of privileged

[1] Dey, Inc., Dey L.P., Inc. and Dey L.P. (collectively Dey) filed a brief in support of Abbott's Request shortly before the United States filed this response. Dey never moved to compel the materials at issue on its own and has no order to appeal. The United States will respond to Dey's pleading as appropriate, although upon preliminary review of Dey's memorandum of law, it does not appear to add anything meaningful to the Court's consideration of this issue.

government documents to bolster one of its proposed defenses to the pricing and marketing conduct alleged in the Amended Complaint. Abbott is endeavoring, *ex post facto*, to weave together disparate threads of government documents and witness testimony to establish some sort of "deliberate" government policy to intentionally over-reimburse for the Abbott drugs in this matter. Abbott's theory is that the alleged policy sanctioned an Abbott-government collaborative effort to "appropriately" compensate Abbott's customers, with Abbott supplying inflated pricing information for the drugs at issue and the government intentionally using that inflated pricing information to reimburse Abbott's customers at a level of Abbott's choosing. The government issued discovery requests to Abbott for evidence (1) demonstrating this alleged policy or arrangement or (2) showing that Abbott's price-reporting practices were designed to meet government public policy goals. Abbott has produced none.

The lack of such evidence is understandable since there never was a government policy to intentionally overpay for the Abbott drugs at issue in this case. If such a policy existed, it would be plainly stated or at least clearly reflected in the hundreds of thousands of pages of public and non-privileged documents produced or available in this matter. It is not. Documents show the opposite is true, *i.e.*, that the government did **not** have a policy of overpaying drug ingredient costs to subsidize practice costs or profit margins for Abbott's customers. *See* Exhibit 1, January 2001 HHS-OIG Report on Medicare Reimbursement of Prescription Drugs at 19 (HCFA states that it "strongly agree[s] with OIG that the use of inflated drug prices is an inappropriate way to compensate practitioners and suppliers for inadequate reimbursement for other practice costs."). In fact, for years the government has recognized the problem of drug overpayments and sought administratively and legislatively to address the issue. Abbott seeks to traverse through

irrelevant, privileged government documents in search of evidence supporting a defense theory that is contradicted by the public record.

Regardless, this discovery dispute is irrelevant to the central issues in the case. This case is not about overpayment for drugs generally. The government has not sued every manufacturer whose AWP exceeded acquisition cost. It is about Abbott's pricing and marketing of the specific drugs in the Amended Complaint. The discovery sought has no material bearing on whether (1) Abbott reported inflated prices for the drugs identified in the Amended Complaint and whether (2) false claims were paid based on the inflated pricing information – the actual claims at issue in the case.

In short, Abbott's Request does not present a controlling issue of law, would not materially advance the resolution of this matter and does not present substantial grounds for difference of opinion. The Court's discovery rulings on the privileged documents were correct, and the request for certification of interlocutory appeal should be denied.

ARGUMENT

I. The Standard for Granting a Petition under 28 U.S.C. § 1292(b)

Section 1292(b) permits appellate review of interlocutory orders under prescribed conditions. The order must involve an issue that (1) involves a controlling question of law; (2) presents a substantial ground for difference of opinion; and (3) provides some prospect for material advancement of the litigation's ultimate termination. 28 U.S.C. § 1292(b). *See In re San Juan DuPont Plaza Hotel Fire Litigation*, 859 F.2d 1007, 1010 n.1 (1st Cir. 1988) (granting petition regarding application of the attorney work product doctrine); *In the Matter of Heddensorf*, 263 F.2d 887 (1st Cir. 1959). Application of these standards is primarily the

function of the district court, which determines in the first instance whether these standards are met. While the Court of Appeals is not bound by the district court's determination, it should give the district court's views "great weight." *Lerner v. Atlantic Richfield Co.*, 690 F.2d 203, 209 (Temp. Emer. Ct. App. 1982). See 9 J. Moore, *Moore's Federal Practice* §110.22[4] (1983) ("[the district court's] considered judgment should be treated with utmost respect.").

The First Circuit disfavors interlocutory appeals. *Lane v. First Nat'l Bank of Boston*, 871 F.2d 166, 175 (1st Cir. 1989). Interlocutory certification "should be used sparingly and only in exceptional circumstances, and where the proposed intermediate appeal presents one or more difficult and pivotal questions of law not settled by controlling authority." *McGillicuddy v. Clements*, 746 F.2d 76, 76 n.1 (1st Cir. 1984) (citation omitted).

As discussed below, the circumstances of this discovery dispute weigh heavily against certifying the questions Abbott raises for interlocutory appeal.[2]

II. The Discovery of Non-Abbott, Privileged Documents Does Not Present a Controlling Issue of Law or Materially Affect the Resolution of this Matter.

Abbott claims that this discovery dispute at issue implicates a controlling question of law and that an appellate ruling in its favor might advance the resolution of this matter are rooted in Abbott's contention that the privileged documents will "likely contain" evidence that the

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[2] The cases cited by Abbott allowing interlocutory appeal of privilege issues are factually distinguishable. In *Flood v. Waste Management, Inc.*, the privileged document at issue was the transcript of a hypnotic session meant to refresh the defendant's recollection of facts directly relevant to the case. 1989 WL 106689 (N.D. Ill. September 14, 1989). As discussed above and below, the non-Abbott privileged documents at issue here are not relevant to the claims as pled. In *Baxter Travenol Laboratories, Inc. v. LeMay*, the privilege issue was certified for appeal because there was a appellate split over the proper interpretation of Supreme Court precedent and the issue was central to the case. 514 F. Supp. 1156 (S.D. Ohio 1981). Those circumstances are not present in the context of Abbott's Request.

government "consciously decided to continue to use a payment methodology that it knew resulted in 'overpayments.'" Request at 7. Abbott claims this evidence "could" substantiate a summary judgment motion, although Abbott never explains exactly how it defeats elements of either the False Claims Act or common law causes of action.

As the government has stated repeatedly during this litigation, this case is about the pricing and marketing of the drugs identified in the United States' complaint.[3] It is not and has never been about the way the government's payment scheme for drugs operated. Abbott's discovery efforts and arguments represent nothing more than a public policy detour from the real issues in this case.

Insofar as the False Claims Act claims are concerned, for example, the elements to be litigated are: (1) whether Abbott submitted false claims and caused false claims to be submitted, (2) whether the specific claims for the drugs at issue were rendered false by Abbott's price reporting and marketing practices and (3) whether Abbott's conduct in reporting false prices and, in some instances, actually submitting claims for the drugs at issue was done with actual knowledge, reckless disregard or deliberate ignorance of the falsity of the claims at issue. Abbott's ability to defend itself turns principally on its ability to explain or legally justify its creation and marketing of the megaspreads on the drugs at issue.

Abbott will not and cannot win summary judgment on any of these elements simply because there are privileged, non-public documents Abbott never possessed or knew about

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[3] The government has already extensively briefed – and will not repeat here – the irrelevance of information in the non-privileged Abbott materials. *See* Exhibit 2, Opposition to Abbott's Renewed Motion to Compel Deliberative Process Evidence (Opposition to Abbott's Renewed Deliberative Process Motion to Compel).

showing, for example, how the government internally examined different ways of reimbursing for drugs.[4] *See, e.g.,* Request at 7. Indeed, there are serious questions as to whether any such documents would even be admissible at trial.

That notwithstanding, to the extent Abbott is allowed to present at trial its "deliberate policy" defense, the documents and evidence it already has – and presented in detail in the Request – are sufficient. Further, Abbott was never prevented from inquiring of government witnesses whether such a deliberate overpayment policy existed during depositions (which is distinguishable from asking about pre-decisional deliberations giving rise to a policy). In short, the preservation of the privilege covering these government documents unrelated to Abbott or the specific Abbott drugs at issue has not prejudiced Abbott from pursuing its defenses.

The Court's decision in this regard is, therefore, not a controlling question of law; at best it relates to one of several defenses for which Abbott possesses an ample factual record to make. As such, an appellate decision in Abbott's favor would not materially advance the resolution of this case.

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[4] The fact that a particular CMS, carrier, or OIG official knew or understood certain facts about drug payment is not, in and of itself, relevant, because "government knowledge" is not a defense under the FCA. *See United States ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991) ("that the relevant government officials knew of the falsity is not in and of itself a defense.").

In certain circumstances, evidence of government knowledge and approval *may* be relevant to the question of whether the defendant possessed the requisite scienter under the FCA. Under the FCA, to negate scienter, Abbott must show (1) that the Government was fully informed by Abbott of the conduct at issue and (2) that the Government *approved* of the conduct at issue. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 861178, at *7 (D. Mass. March 22, 2007) (denying motion to dismiss California False Claims Act claim, noting that government approval of the particulars is necessary to negate scienter)*; United States ex rel. Tyson v. Amerigroup,* 2007 WL 781729, at *20 (N.D. Ill. March 13, 2007) (proper test is whether the government knew and approved the particulars of defendant's conduct.)

III. The Discovery of Non-Abbott, Privileged Documents Does Not Present Substantial Grounds for Difference of Opinion Regarding the Court's Decision.

Abbott's claim that the discovery dispute at issue implicates a substantial grounds for difference of opinion rests on its contention that an appellate court must weigh in now on whether the government maintains the deliberative process privilege when it sues persons or companies who defraud it. Abbott argues that this Court is at odds with other jurisdictions when it concluded that a government fraud suit does not vitiate the deliberative process privilege.

This Court's rejection of Abbott's waiver argument is consistent with other deliberative process case law. The United States has established clearly and unambiguously that the government does not waive its deliberative process privilege when it sues a defendant for fraud. *See Landry v. FDIC*, 204 F3d 1125, 1136 (D.C. Cir. 2000); *United States v. Hooker Chemicals and Plastics*, 114 F.R.D. 100, 103 (W.D.N.Y. 1987). It is only when the government's subjective motivation is the subject matter at issue that Courts allow for blanket waiver of the deliberative process privilege. *See In re Subpoena Duces Tecum Served on the Comptroller of the Treasury,* 145 F.3d 1422, 1425 (D.C. Cir. 1998) (privilege must give way when issues in case make deliberative processes the issue, such as in Title VII discrimination cases). It is Abbott's price reporting and marketing conduct, not government's drug payment policies manufactured from non-public information, that is the focus of this litigation. Thus, there is no conflict or substantial grounds for difference of opinion since the authority permitting waiver of the deliberative process privilege was inapposite.

IV. The Privilege Was Asserted Properly and Is Not a Proper Basis for Interlocutory Appeal.

The Court held the deliberative process applied to the non-Abbott documents at issue, but precluded them from Magistrate Judge Bowler's *in camera* review of deliberative process materials. The parties already briefed whether the deliberative process privilege was properly asserted. *See, e.g.,* Exhibit 2, Opposition to Abbott's Renewed Deliberative Process Motion to Compel at 18-23. Abbott's Request merely regurgitates its previous arguments and offers no new or compelling basis for certifying the issue for appeal. The Court's decision should stand.

CONCLUSION

For the reasons set forth above, the United States respectfully requests that the Court deny Abbott's request for certification of interlocutory appeal.

Respectfully submitted,

For the United States of America,

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above **UNITED STATES' RESPONSE TO ABBOTT LABORATORIES INC.'S REQUEST FOR CERTIFICATION OF INTERLOCUTORY APPEAL** to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Gejaa T. Gobena
Dated: May 9, 2008 Gejaa T. Gobena